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Contact and information after self-harm pilot study

Submission date	Recruitment status	[ ] Prospectively registered
24/06/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
24/06/2010	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/07/2013	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
8434

Study information

Scientific Title

A pilot study of a contact and information based intervention to reduce repeat self-harm

Study objectives
The study is funded by the National Institute of Health Research and will be carried out on patients who have recently attended the emergency departments at two hospitals in Manchester following an episode of self-harm.

We plan to recruit between 50 - 100 people over a three month period who have been discharged from the emergency department following self-harm, into the intervention group or the control group. The intervention group will receive an information leaflet providing details of local and national support agencies, followed by two phone calls, and then letters intermittently up to 12 months after recruitment. Both groups will receive their treatment as usual. The rationale for the intervention is to provide contact and facilitate patient access to appropriate treatment. The phone calls and letters will be from a mental health clinician. The main aim of this study is to inform the implementation of a large multicentre randomised control study. We will also investigate whether the intervention reduces repetition of self-harm.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West 9 Research Ethics Committee - Greater Manchester West approved on the 24th May 2010 (ref: 10/H1014/35)

Study design
Single centre randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Mental Health Research Network; Subtopic: Suicide and self-harm; Disease: Suicide and self harm

Interventions
Patients in the intervention group will receive two phone calls from a clinical researcher soon after hospital attendance, an information leaflet listing local sources of help, and then letters intermittently up to 12 months after recruitment, as well as treatment as usual.

Patients in the control group will receive treatment as usual.

Follow-up length: 12 months
Study entry: single randomisation only

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
To assess the feasibility of a randomised controlled trial (RCT), in particular, recruitment at 6 and /or 12 months

Secondary outcome measures
1. At 12 months we will assess the acceptability of the intervention and help refine it
2. Proportion of patients with at least one repetition of self-harm within 6 and/or 12 months
3. Assess resource use in order to pilot collection of such data

Overall study start date
01/04/2010

Completion date
30/09/2011

Eligibility

Key inclusion criteria
1. Adults aged over 18 years, either sex
2. Present to the study hospitals with self-harm

Recruitment may take up to three months or we may achieve our target sample size at an earlier stage. "Self-harm" is defined as "an act of intentional self-injury or poisoning irrespective of the apparent purpose of the act". This includes attempts regardless of suicidal intent or medical seriousness and as a definition is in line with that used by NICE guidelines on the short term management of self-harm.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 100; UK sample size: 100

Key exclusion criteria
1. Psychiatric in-patients
2. No fixed abode
3. Do not have telephone access
4. Unable to give informed consent during the first telephone call
5. Have been approached at an earlier stage in the study and had refused consent
6. Not able to understand the English language

Date of first enrolment
01/04/2010

Date of final enrolment
30/09/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford Road
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation
University of Manchester (UK)

Sponsor details
Centre for Suicide Prevention
Room 2.320
University Place
Oxford Road
Manchester
England
United Kingdom
M13 9PL

Sponsor type
University/education

Website
http://www.manchester.ac.uk/

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Programme Grant for Applied Research (PGfAR)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2013		Yes	No